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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,104	10/28/2003	Jose Andres Morales Garzon	44862 / 00001	4820

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,104	GARZON ET AL.	
	Examiner	Art Unit	
	A R Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~6/04~~ 5-10-04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending.
Submitted Information Disclosure Statement (I.D.S) is noted.

Specification

The disclosure is objected to because of the following informalities: There are foreign terms present in the specification, please provide the accurate translation between Spanish and English, for example see page 8 line 18, or top of page 14..

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 provides for the use of "imunoglobulines", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). This affects claims 2-8.

Claim 2 is vague and indefinite for recitation of "exhaustive vaccination", this is a relative term, and is subject to varied interpretation. What does this mean? The claim has been interpreted in light of specification and since the disclosure does not set forth the intended meaning of the said term, hence, the claim is indefinite.

Claim 4 is objected to for recitation of "antibody title", this has no meaning. Is antibody titer intended?

Claim 8 is vague and indefinite for recitation of "lower", this is a relative term, and is subject to varied interpretation.

Claim Rejections - 35 USC § 112

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is deficient in providing adequate teaching for the claimed invention. The specification sets out a general disclosure where it follows methods well known to those ordinary skills in the art to establish that antibodies can be raised in egg yolk. The teaching is rather disjointed. What is not provided is the specific PRRSV antigen that was used to generate antibodies, if any. If the whole virus was utilized then it is not clear what strain was used, and whether or not the antibody response was to the whole virus or a specific antigen type. None of these points are explained. In addition, the specification broadly indicates that sows received a dose of Ig against PRRS (see page 7); the specification goes on to say that sows were bled to determine the antibodies against

PRRS. There is no teaching whether or not sows were initially infected or whether or not the bleeding experiment is a clearance experiment to determine the Ig's half-life. Still further, the specification is non-enabling for the treatment in general, and prevention of PRRSV in particular. There is no indication that any PRRSV infected sows have been treated with the egg yolk generated Igs, and whether or not any PRRSV infection was treated. The figures provided are confusing. The Figure 1 indicates determination of antibodies in serum of pigs treated with two different doses of immunoglobulins, what does this mean? In addition, Figure 2 indicates that presence of antibodies against PRRS measured by the ELISA test, now, it is not clear whether the sows were PRRSV infected or whether sows antibodies reacted with PRRSV antigen? Also, the specification does not provide any challenge study that would merit the conclusion that PRRSV has been prevented. Applicants are reminded that this field is highly unpredictable. Although raising antibodies in egg yolk is routine, if the antigen is not known and no study is conducted to show whether or not the Igs raised are actually efficacious against a particular infection, then one of ordinary skill in the art would be forced to conduct large quantity of undue experimentation to enable the claimed invention. The PRRSV is a RNA virus that is under evolutionary pressure and normally mutates. There are no teachings in the specification that the produced Igs have treated any PRRSV infection, or an antibody rose against any specific antigen. Undue experimentations would be required since the specification provides no working examples for the now claimed invention, and the field vaccine development and virology is rather unpredictable

Applicants have general statements regarding the protection and treatment of PRRSV. However with regard to an unpredictable field, this does not constitute an adequate disclosure.

See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). Applicants cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim1 is are rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al (WO 01/59077).

The product being claimed now is clearly anticipated by the above cited reference. Collins et al taught antigens of PRRSV, they disclosed antibodies against PRRSV, and method of making and using antibodies against PRRSV. Moreover, they taught method of detecting PRRSV (see the claims). The product disclosed in the above cited reference appears to be

identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Still further, the claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al (US Patent No. 5,846,805), and Yokoyama et al (Poultry Sci. 1993).

The claims are directed to use of antibodies for the treatment of pigs infected with PRRSV.

Collins et al taught PRRSV isolate including inactivated vaccine (see Column 3, lines 34-45), and disclosed how to generate antibodies and utilize the antibodies in both induction of immune response and utilize the antibodies in detection and diagnostic assay (see the claims, and

Column 5, and Column 6, lines 1-26). This differs only to the extent that they did not taught collecting antibodies form egg yolk.

Yokoyama et al taught a method of purification of fowl egg yolk immunoglobulin including utilizing hydroxypropylmethylcellulose (see the abstract). This only differs since they did not teach PRRSV.

However, one of ordinary skill in the art at the time of filing would have been motivated to utilize the method taught by Yokoyama et al and incorporate the virus taught by Collins to obtain a method to raise antibodies to treat pigs for PRRSV. One of ordinary skill in the art being familiar with the state of the art as stated above would not have anticipated any unexpected results. The antigens are taught, the method of raising antibodies is also taught. Hence, the invention as a whole is prima facie obvious absent unexpected results.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunchar et al (US Patent No. 6,217,865), and Yokoyama et al (Poultry Sci. 1993).

Hunchar et al taught a method of "exhaustive vaccination" and raising antibodies in egg yolk against all types of antigens including virus. This differs since they did not teach hydroxypropylmethylcellulose.

Yokoyama et al taught a method of purification of fowl egg yolk immunoglobulin including utilizing hydroxypropylmethylcellulose (see the abstract). This only differs since they did not teach viral antigen.

However, one of ordinary skill in the art at the time of filing would have been motivated to utilize the method taught by Yokoyama et al and incorporate the virus taught by Hunchar et al

to obtain a method to raise antibodies to treat against viral antigens. Applicants are reminded that Hunchar et al is pioneering invention and the viral antigen incorporates PRRSV antigen. One of ordinary skill in the art being familiar with the state of the art as stated above would not have anticipated any unexpected results. The antigens are taught, the method of raising antibodies is also taught. Hence, the invention as a whole is prima facie obvious absent unexpected results.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al (WO 01/59077), and Yokoyama et al (Poultry Sci. 1993).

Collins et al taught antigens of PRRSV, they disclosed antibodies against PRRSV, and method of making and using antibodies against PRRSV. Moreover, they taught method of detecting PRRSV (see the abstract and the claims).

Yokoyama et al taught a method of purification of fowl egg yolk immunoglobulin including utilizing hydroxypropylmethylcellulose (see the abstract). This only differs since they did not teach viral antigen.

However, one of ordinary skill in the art at the time of filing would have been motivated to utilize the method taught by Yokoyama et al and incorporate the virus and antigens taught by Collins et al to obtain a method to raise antibodies to treat against PRRSV antigens. One of ordinary skill in the art being familiar with the state of the art as stated above would not have anticipated any unexpected results. The antigens are taught, the method of raising antibodies is also taught. Hence, the invention as a whole is prima facie obvious absent unexpected results.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi
5/16/2005

ALI R. SALIMI
PRIMARY EXAMINER